UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI

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| JOSE VILLARREAL, on behalf of himself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>BAYER U.S. LLC,<br><br>Defendant. | Case No.<br><br>**CLASS ACTION COMPLAINT**<br><br>DEMAND FOR JURY TRIAL |

Plaintiff Jose Villarreal ("Plaintiff") brings this action on behalf of himself and all others similar situated, against Bayer U.S. LLC ("Defendant" or "Bayer"). Plaintiff makes the following allegations based upon (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

## INTRODUCTION

1. This action arises out of Bayer's manufacture and distribution of the over-the-counter anti-fungal medications Tinactin ("Tinactin") and Lotrimin Anti-Fungal ("Lotrimin AF") spray products (the "Recalled Sprays") without disclosing that they contain high levels of benzene, a known human carcinogen. The Recalled Sprays include: (1) Lotrimin AF Athlete's Foot Powder Spray; (2) Lotrimin AF Jock Itch Foot Powder Spray; (3) Lotrimin AF Athlete's Foot Deodorant Powder Spray; (4) Lotrimin AF Athlete's Foot Liquid Spray; (5) Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray; (6) Tinactin Jock Itch Powder Spray; (7) Tinactin Athlete's Deodorant Foot Powder Spray; (8) Tinactin Athlete's Foot Powder Spray; and (9) Tinactin Athlete's Foot Liquid Spray.

2. Benzene is a known human carcinogen.[1] Benzene is proven to cause cancer in humans, including blood cancers such as leukemia.[2] In addition to cancer, direct exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation.[3] Because of these proven effects, the FDA has adopted a limit for benzene in products of 2 parts per million (ppm).[4]

3. Bayer knew or should have known of the dangerous and carcinogenic effects of benzene and should have known that it was producing products that contained benzene. Nevertheless, Bayer produced, distributed, and sold millions of cans of Tinactin and Lotrimin AF sprays that contained benzene.

4. Plaintiff is a purchaser and user of the Recalled Sprays. Plaintiff purchased the recalled sprays to treat conditions the Recalled Sprays were intended to treat and used the Recalled Sprays in accordance with the directions provided on their packaging. Plaintiff did so because he believed the Recalled Sprays had been manufactured using acceptable standards and practices and that they were safe for human use. However, in reality Plaintiff bought toxic, dangerous, unmerchantable products unfit for their intended purpose and use. Plaintiff would not have purchased and used the Recalled Sprays had he known they were unsafe. Plaintiff was therefore harmed at the point of purchase of the Recalled Sprays when he did not receive the benefit of the bargain.

5. Plaintiff brings this action on behalf of himself, the Classes, and Subclasses for equitable relief and to recover damages or equitable relief for: (i) breach of express warranty; (ii)

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[1] National Cancer Institute, Cancer-Causing Substances, Benzene. https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene (last accessed July 19, 2021).

[2] *Id.*

[3] Centers for Disease Control and Prevention, Facts About Benzene, https://emergency.cdc.gov/agent/benzene/basics/facts.asp (last accessed July 19, 2021).

[4]

breach of implied warranty; (iii) violation of the consumer protection statutes of the states of which Plaintiff are citizens; (iv) fraudulent concealment; and (v) unjust enrichment.

## PARTIES

6. Plaintiff Jose Villarreal is a citizen and resident of Boone County, Missouri.

7. Defendant Bayer U.S. LLC is a Delaware corporation with its principal place of business located in Whippany, New Jersey.

## JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), because this is a class action with aggregate claims exceeding $5,000,000.00, exclusive of interest and costs, and the Plaintiff and most members of the proposed Class are citizens of states different from the Defendant.

9. The Court has personal jurisdiction over Bayer because Bayern conducts business in this District, marketed the Recalled Sprays in this District, and has availed itself of the Missouri markets through promotion, marketing, and sales of the Recalled Sprays to render exercise by this Court proper.

10. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, because Bayer transacts business in, is found in, and/or has agents in this District, and because some of the actions giving rise to this complaint took place within this District.

## FACTUAL BACKGROUND

### I. TINACTIN AND LOTRIMIN AF

11. Tinactin and Lotrimin AF are over-the-counter anti-fungal medication brands owned, manufactured, and distributed by Defendant Bayer. Tinactin and Lotrimin AF contain

different active ingredients but are generally used to address the same conditions. For example, both Tinactin and Lotrimin AF treat "Athlete's Foot", "Ringworm", and "Jock Itch." Additionally, both Tinactin and Lotrimin AF can be used preventively (*i.e.*, to prevent the development of conditions like athlete's foot and jock itch) or to treat and resolve already-developed conditions. Defendant Bayer has owned, manufactured, and distributed the Tinactin and Lotrimin AF brands since 2014 when it acquired both brands as part of its acquisition of Merck & Co. Inc.'s consumer products line.[5] Tinactin and Lotrimin AF are both manufactured, distributed, and sold as creams and sprays.

## A. TINACTIN SPRAYS

### i. TINACTIN ATHLETE'S FOOT LIQUID SPRAY

12. Tinactin Athlete's Foot Liquid Spray's "Drug Facts" indicate it should be used in the following ways: (1) "in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)"; (2) to "help[] prevent most athlete's foot with daily use"; and (3) "for effective relief of itching, burning, and cracking."[6] The directions included with Tinactin Athlete's Foot Liquid Spray cans directed users to use the product "twice daily . . . for 4 weeks."[7]

13. The following is an image of the Tinactin Athlete's Foot Liquid Spray label as presented by Bayer during the Class Period:

[5] *Bayer to acquire consumer care business of US-based Merck & Co., Inc. and to engage in strategic pharma cooperation in the field of sGC modulators*, BAYER PRESS RELEASE (May 6, 2014), https://media.bayer.com/baynews/baynews.nsf/id/Bayer-acquire-consumer-business-US-based-Merck-Co-Inc-engage-strategic-pharma-cooperation-field-sGC (accessed Oct. 26, 2021).
[6] https://www.livewell.bayer.com/deco/omr/Tinactin_Liquid_Spray_drugfacts.pdf
[7] https://www.livewell.bayer.com/deco/omr/Tinactin_Liquid_Spray_drugfacts.pdf;

*TINACTIN ATHLETE'S FOOT LIQUID SPRAY LABEL*

| **Drug Facts** |
|---|
| ***Active ingredient*** **Purpose**<br>(To Deliver)Tolnaftate 1%.....Antifungal |
| ***Uses*** ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis) ▪ helps prevent most athlete's foot with daily use<br>▪ for effective relief of itching, burning, and cracking |
| ***Warnings***<br>**For external use only**<br>**Flammable:** Do not use near heat, flame, or while smoking<br>**Do not use** on children under 2 years of age unless directed by a doctor. |
| **When using this product**<br>▪ avoid contact with the eyes<br>▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.<br>▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. |
| **Stop use and ask a doctor if** ▪ irritation occurs ▪ there is no improvement within 4 weeks |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions*** ▪ wash affected area and dry thoroughly<br>▪ shake can well and spray a thin layer over affected area twice daily (morning and night)<br>▪ supervise children in the use of this product<br>▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily<br>▪ use daily for 4 weeks; if condition persists longer, ask a doctor<br>▪ to prevent athlete's foot, apply once or twice daily (morning and/or night)<br>▪ this product is not effective on the scalp or nails |
| ***Other information*** store between 20°to 25℃ (68°to 77℉) |
| ***Inactive ingredients*** butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (29% v/v) |
| ***Questions?*** 1-866-360-3266 |

### ii. TINACTIN ATHLETE'S FOOT POWER SPRAY

14. Tinactin Athlete's Foot Power Spray's "Drug Facts" indicate it should be used in the following ways: (1) "in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)"; (2) to "help[] prevent most athlete's foot with daily use"; and (3) "for effective relief of itching, burning, and cracking."[8] The directions included with Tinactin Athlete's Foot Liquid Spray cans directed users to use the product "twice daily . . . for 4 weeks."[9]

15. The following is an image of the Tinactin Athlete's Foot Power Spray label as presented by Bayer during the Class Period:

*TINACTIN ATHLETE'S FOOT POWER SPRAY LABEL*

| |
|---|
| ***Drug Facts*** |
| ***Active ingredient*** ***Purpose***<br>(To Deliver) Tolnaftate 1%.....Antifungal |
| ***Uses*** ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)<br>▪ helps prevent most athlete's foot with daily use<br>▪ for effective relief of itching, burning and cracking |
| ***Warnings***<br>**For external use only**<br>**Flammable:** Do not use near heat, flame, or while smoking<br>Do not use on children under 2 years of age unless directed by a doctor. |
| **When using this product** ▪ avoid contact with the eyes<br>▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.<br>▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. |
| **Stop use and ask a doctor if** ▪ irritation occurs ▪ there is no improvement within 4 weeks |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions*** ▪ wash the affected area and dry thoroughly<br>▪ shake can well and spray a thin layer over affected area twice daily (morning and night)<br>▪ supervise children in the use of this product<br>▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily<br>▪ use daily for 4 weeks; if condition persists longer, ask a doctor<br>▪ to prevent athlete's foot, apply once or twice daily (morning and/or night)<br>▪ this product is not effective on the scalp or nails |
| ***Other information*** store between 20° to 25°C (68° to 77°F) |
| ***Inactive ingredients*** butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (11% v/v), talc |
| ***Questions?*** 1-866-360-3266 |

[8] https://www.livewell.bayer.com/deco/omr/Tinactin_AF_Powder_Spray_drugfacts.pdf
[9] *Id.*

### iii. TINACTIN ATHLETES FOOT DEODORANT SPRAY

16. Tinactin Athletes Foot Deodorant Spray's "Drug Facts" indicate it should be used in the following ways: (1) "in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)"; (2) to "help[] prevent most athlete's foot with daily use"; and (3) "for effective relief of itching, burning, and cracking."[10] The directions included with Tinactin Athlete's Foot Liquid Spray cans directed users to use the product "twice daily . . . for 4 weeks."[11]

17. The following is an image of the Tinactin Athletes Foot Deodorant Spray label as presented by Bayer during the Class Period:

*TINACTIN ATHLETES FOOT DEODORANT SPRAY LABEL*

| ***Drug Facts*** |
|---|
| ***Active ingredient*** (To Deliver) Tolnaftate 1%..... ***Purpose*** Antifungal |
| ***Uses***<br>• proven clinically effective in the treatment of most athlete's foot (tinea pedis) and ringworm (tinea corporis)<br>• helps prevent most athlete's foot with daily use<br>• for effective relief of itching, burning, and cracking |
| ***Warnings***<br>**For external use only** |
| **Flammable:** Do not use near heat, flame, or while smoking |
| **Do not use** on children under 2 years of age unless directed by a doctor. |
| **When using this product**<br>• avoid contact with the eyes<br>• use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.<br>• contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120℉. |
| **Stop use and ask a doctor if**<br>• irritation occurs<br>• there is no improvement within 4 weeks |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions***<br>• wash the affected area and dry thoroughly<br>• shake can well and spray a thin layer over affected area twice daily (morning and night)<br>• supervise children in the use of this product<br>• for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily<br>• use daily for 4 weeks; if condition persists longer, ask a doctor<br>• to prevent athlete's foot, apply once or twice daily (morning and/or night)<br>• this product is not effective on the scalp or nails |
| ***Other information***<br>• store between 20°to 25℃ (68°to 77°F) |
| ***Inactive Ingredients***<br>butylated hydroxytoluene, fragrance, isobutane, PPG-12-buteth-16, SD alcohol 40-B (10.5% v/v),talc |
| ***Questions?*** 1-866-360-3266 |

[10] https://www.livewell.bayer.com/deco/omr/Tinactin_Deodorant_Powder_Spray_drugfacts.pdf
[11] *Id.*

### iv. TINACTIN JOCK ITCH POWDER SPRAY

18. Tinactin Jock Itch Powder Spray's "Drug Facts" indicate it should be used in the following ways: (1) "cures most jock itch"; and (2) "for effective relief of itching, chafing and burning."[12] The directions included with Tinactin Athlete's Foot Liquid Spray cans directed users to use the product "twice daily . . . for 2 weeks."[13]

19. The following is an image of the Tinactin Jock Itch Powder Spray label as presented by Bayer during the Class Period:

*TINACTIN JOCK ITCH POWDER SPRAY LABEL*

| |
|---|
| ***Drug Facts*** |
| ***Active ingredient*** ***Purpose***<br>(To Deliver) Tolnaftate 1%.....Antifungal |
| ***Uses***<br>▪ cures most jock itch<br>▪ for effective relief of itching, chafing and burning |
| ***Warnings***<br>**For external use only**<br>**Flammable:** Do not use near heat, flame, or while smoking<br>**Do not use** on children under 2 years of age unless directed by a doctor. |
| **When using this product**<br>▪ avoid contact with the eyes<br>▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.<br>▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. |
| **Stop use and ask a doctor if** ▪ irritation occurs ▪ there is no improvement within 2 weeks |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions***<br>▪ wash the affected area and dry thoroughly<br>▪ shake can well and spray a thin layer over affected area twice daily (morning and night)<br>▪ supervise children in the use of this product<br>▪ use daily for 2 weeks; if condition persists longer, ask a doctor<br>▪ this product is not effective on the scalp or nails |
| ***Other information*** store between 20°to 25℃ (68°to 77℉) |
| ***Inactive ingredients*** butylated hydroxytoluene, isobutane, PPG-12-buteth-16, SD alcohol 40-B (11% v/v), talc |
| ***Questions?*** 1-866-360-3266 |

[12] https://www.livewell.bayer.com/deco/omr/Tinactin_JI_Powder_Spray_drugfacts.pdf
[13] *Id.*

## B. LOTRIMIN AF SPRAYS

### i. LOTRIMIN AF ATHLETE'S FOOT POWDER SPRAY

20. Lotrimin AF Athlete's Foot Powder Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking, burning, scaling and discomfort" [14]

21. The following is an image of the Lotrimin AF Athlete's Foot Powder Spray label as presented by Bayer during the Class Period:

*LOTRIMIN AF ATHLETE'S FOOT POWDER SPRAY LABEL*

| |
|---|
| ***Drug Facts*** |
| ***Active ingredient*** (To Deliver) Miconazole nitrate 2%..... ***Purpose*** Antifungal |
| ***Uses***<br>▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)<br>▪ for effective relief of itching, cracking, burning, scaling and discomfort |
| ***Warnings***<br>**For external use only**<br>**Flammable:** Do not use near heat, flame, or while smoking<br>**Do not use** on children under 2 years of age unless directed by a doctor. |
| **When using this product** ▪ avoid contact with the eyes<br>▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.<br>▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. |
| **Stop use and ask a doctor if** ▪ irritation occurs<br>▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch) |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions*** ▪ wash the affected area and dry thoroughly<br>▪ shake can well and spray a thin layer over affected area twice daily (morning and night)<br>▪ supervise children in the use of this product<br>▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily<br>▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks<br>▪ if condition persists longer, ask a doctor<br>▪ this product is not effective on the scalp or nails |
| ***Other information*** store between 20° to 25°C (68° to 77°F) |
| ***Inactive ingredients*** isobutane, SD alcohol 40-B (8% v/v), stearalkonium hectorite, talc |
| ***Questions?*** 1-866-360-3266 |

[14] https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Powder_Spray_DrugFacts.pdf

### ii. LOTRIMIN AF JOCK ITCH ATHLETE'S FOOT POWDER SPRAY

22. Lotrimin AF Jock Itch Athlete's Foot Powder Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most jock itch (tinea cruris)"; and (2) "for effective relief of itching, burning, scaling and discomfort, and chafing associated with jock itch."[15] The label directs users to use the product "twice daily . . . for 2 weeks." [16]

23. The following is an image of the Lotrimin AF Jock Itch Athlete's Foot Powder Spray label as presented by Bayer during the Class Period:

*LOTRIMIN AF JOCK ITCH ATHLETE'S FOOT POWDER SPRAY LABEL*

| |
|---|
| ***Drug Facts*** |
| ***Active ingredient*** ***Purpose***<br>(To Deliver) Miconazole nitrate 2%.....Antifungal |
| ***Uses***<br>▪ proven clinically effective in the treatment of most jock itch (tinea cruris)<br>▪ for effective relief of itching, burning, scaling and discomfort, and chafing associated with jock itch |
| ***Warnings***<br>**For external use only**<br>**Flammable:** Do not use near heat, flame, or while smoking<br>**Do not use** on children under 2 years of age unless directed by a doctor. |
| **When using this product** ▪ avoid contact with the eyes<br>▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.<br>▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. |
| **Stop use and ask a doctor if** ▪ irritation occurs ▪ there is no improvement within 2 weeks |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions***<br>▪ wash the affected area and dry thoroughly<br>▪ shake can well and spray a thin layer over affected area twice daily (morning and night)<br>▪ supervise children in the use of this product<br>▪ use daily for 2 weeks<br>▪ if condition persists longer, ask a doctor<br>▪ this product is not effective on the scalp or nails |
| ***Other information***<br>store between 20°to 25℃ (68°to 77℉) |
| ***Inactive ingredients*** isobutane, SD alcohol 40-B (8% v/v), stearalkonium hectorite, talc |
| ***Questions?*** 1-866-360-3266 |

[15] https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_JI_Powder_Spraydrug_facts.pdf
[16] *Id.*

### iii. LOTRIMIN AF ATHLETE'S FOOT DEODORANT POWDER SPRAY

24. Lotrimin AF Athlete's Foot Deodorant Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking, burning, scaling and discomfort."[17] The label directs users to use the product "daily for 4 weeks" for "athlete's foot and ringworm" and to use the product "daily for 2 weeks" for "jock itch."[18]

25. The following is an image of the Lotrimin AF Athlete's Foot Deodorant Spray label as presented by Bayer during the Class Period:

*LOTRIMIN AF ATHLETE'S FOOT DEODORANT SPRAY'S LABEL*

| |
|---|
| ***Drug Facts*** |
| ***Active ingredient*** ***Purpose***<br>(To Deliver) Miconazole nitrate 2%.....Antifungal |
| ***Uses***<br>▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)<br>▪ for effective relief of itching, cracking, burning, scaling and discomfort |
| ***Warnings***<br>**For external use only**<br><br>**Flammable:** Do not use near heat, flame, or while smoking<br><br>**Do not use** on children under 2 years of age unless directed by a doctor. |
| **When using this product** ▪ avoid contact with the eyes<br>▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.<br>▪ contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. |
| **Stop use and ask a doctor if** ▪ irritation occurs<br>▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch) |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions*** ▪ wash the affected area and dry thoroughly<br>▪ shake can well and spray a thin layer over affected area twice daily (morning and night)<br>▪ supervise children in the use of this product<br>▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily<br>▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks<br>▪ if condition persists longer, ask a doctor<br>▪ this product is not effective on the scalp or nails |
| ***Other information***<br>store between 20°to 25℃ (68°to 77℉) |
| ***Inactive ingredients*** fragrance, isobutane, SD alcohol 40-B (8% v/v), stearalkonium hectorite, talc |
| ***Questions?*** 1-866-360-3266 |

[17] https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Deodorant_Powder_Spray_Drug_Facts.pdf
[18] *Id.*

### iv. LOTRIMIN AF ATHLETE'S FOOT LIQUID SPRAY

26. Lotrimin AF Athlete's Foot Liquid Spray's label lists the following uses: (1) "proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)"; and (2) "for effective relief of itching, cracking, burning, scaling and discomfort."[19] The label directs users to use the product "daily for 4 weeks" for "athlete's foot and ringworm" and to use the product "daily for 2 weeks" for "jock itch."[20]

27. The following is an image of the Lotrimin AF Athlete's Foot Liquid Spray label as presented by Bayer during the Class Period:

*LOTRIMIN AF ATHLETE'S FOOT LIQUID SPRAY LABEL*

| |
|---|
| ***Drug Facts*** |
| ***Active ingredient*** ***Purpose***<br>(To Deliver) Miconazole nitrate 2%.....Antifungal |
| ***Uses*** ▪ proven clinically effective in the treatment of most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis)<br>▪ for effective relief of itching, cracking, burning, scaling and discomfort |
| ***Warnings***<br>**For external use only**<br>**Flammable:** Do not use near heat, flame, or while smoking<br>**Do not use** on children under 2 years of age unless directed by a doctor. |
| **When using this product** ▪ avoid contact with the eyes<br>▪ use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.<br>▪ do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F. |
| **Stop use and ask a doctor if** ▪ irritation occurs<br>▪ there is no improvement within 4 weeks (for athlete's foot and ringworm) or 2 weeks (for jock itch) |
| **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. |
| ***Directions*** ▪ wash the affected area and dry thoroughly<br>▪ shake can well and spray a thin layer over affected area twice daily (morning and night)<br>▪ supervise children in the use of this product<br>▪ for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily<br>▪ for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks<br>▪ if condition persists longer, ask a doctor<br>▪ this product is not effective on the scalp or nails |
| ***Other information*** store between 20° to 25°C (68° to 77°F) |
| ***Inactive ingredients*** dimethyl ether, polyoxyl 15 hydroxystearate, SD alcohol 40-B (16.5% v/v) |
| ***Questions?*** 1-866-360-3266 |

[19] https://www.livewell.bayer.com/deco/omr/Lotrimin_AF_Liquid_Spraydrug_facts.pdf
[20] *Id.*

### v. LOTRIMIN AF ATHLETE'S FOOT DAILY PREVENTION DEODORANT POWDER SPRAY

28. Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray's label listed the following uses: (1) "clinically proven to prevent most athlete's foot with daily use."[21] The label directed users to use the product "once or twice daily."[22]

29. The following is an image of Lotrimin AF Athlete's Foot Daily Prevention Deodorant Powder Spray's label as presented by Bayer on the product during the Class Period:

*LOTRIMIN AF ATHLETE'S FOOT DAILY PREVENTION DEODORANT POWDER SPRAY LABEL*

**Drug Facts**

**Active ingredient** — **Purpose**
(To Deliver) Tolnaftate 1% ..... Antifungal

**Use**
- clinically proven to prevent most athlete's foot with daily use

**Warnings**
**For external use only**

**Flammable:** Do not use near heat, flame, or while smoking

**Do not use** on children under 2 years of age unless directed by a doctor

**When using this product**
- avoid contact with the eyes
- use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

**Stop use and ask a doctor if** irritation occurs.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**
- to prevent athlete's foot, wash the feet and dry thoroughly.
- shake can well and spray a thin layer of the product on the feet once or twice daily (morning and/or night).
- supervise children in the use of this product.
- pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.

**Other information**
- store between 20° to 25°C (68° to 77°F)

**Inactive ingredients** butylated hydroxytoluene, fragrance, isobutane, PPG-12-buteth-16, SD alcohol 40-B (10.5% v/v), talc

**Questions?** 1-866-360-3266

[21] https://www.lotrimin.com/our-products/daily-prevention-athlete-deodorant-powder-spray
[22] *Id.*

## II. BENZENE

30. Benzene is a colorless, flammable liquid which can occur from natural processes such as forest fires or volcanoes, or from artificial human manufacturing activities.[23]

31. Benzene can be absorbed through the skin during contact with a source of benzene.[24]

32. Benzene is a known human carcinogen, meaning that it is known to cause cancer. Studies have shown that rates of leukemia are higher in humans exposed to high levels of benzene.[25] Studies have also suggested links to the following cancers: (1) childhood leukemia; (2) acute lymphocytic leukemia; (3) chronic lymphocytic leukemia; and (4) other blood-related cancers such as multiple myeloma and non-Hodgkin lymphoma in adults (collectively, "Benzene-caused Cancer(s)").[26]

33. Lab studies on labs rats and mice have shown that when benzene is inhaled or swallowed it causes different types of tumors to develop.[27] These results support the finding of an excess risk of leukemia in humans.[28]

34. The United States Department of Health and Human Services (DHHS) has determined that benzene causes cancer in humans.[29] Long-term exposure to high levels of benzene in the air can cause leukemia, cancer of the blood-forming organs.[30]

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[23] https://www.cancer.org/cancer/cancer-causes/benzene.html
[24] *Id.*
[25] *Id*.
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] https://emergency.cdc.gov/agent/benzene/basics/facts.asp
[30] *Id.*

35. Similarly, the World Health Organization ("WHO") and the International Agency for Research on Cancer ("IARC") have classified benzene as a Group 1 compound thereby defining it as "carcinogenic to humans."3

36. Benzene's carcinogenic effects are why the FDA classifies benzene as a "Class 1 solvent", meaning that benzene "should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicity ... However, if their use is unavoidable in order to produce a drug product with a significant therapeutic advance, then their levels should be restricted" and benzene is restricted under such guidance to 2 parts per million ("ppm").

37. The National Institute for Occupational Safety and Health ("NIOSH") recommends protective equipment be worn by workers expecting to be exposed to benzene at concentrations of 0.1 ppm and defines "inhalation, skin absorption, ingestion, skin and/or eye contact" as exposure routes.

## SUBSTANTIVE ALLEGATIONS

## III. BAYER'S TINACTIN AND LOTRIMIN AF SPRAYS CONTAIN BENZENE

38. On October 1, 2021 Bayer announced a recall (the "Recall Announcement") of "all unexpired Lotrimin® AF and Tinactin® spray products with lot numbers beginning with TN, CV or NAA, distributed between September 2018 to September 2021"[31] because Bayer's testing had detected the toxic carcinogen benzene in samples of Tinactin and Lotrimin AF sprays. While the limiting language (*i.e.*, those "with lot numbers beginning with TN, VA or NAA") of Bayer's press release deceptively suggests that the Recalled Sprays represent only a portion of the Tinactin and Lotrimin AF sprays manufactured from 2018 through 2021, upon information and belief, the

[31] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene

Recalled Sprays represents all unexpired Tinactin and Lotrimin AF sprays manufactured between 2018 and 2021.

39. Bayer's Recall Announcement noted that "[b]enzene is not an ingredient in any of Bayer Consumer Health products"32 which means that the manufacturing process designed, implemented, and used by Bayer to manufacture the Recalled Sprays is responsible for allowing the carcinogen benzene to make its way into the Recalled Sprays.

40. As a result of Bayer's failure to keep benzene out of the Recalled Sprays, millions of consumers have been repeatedly and consistently exposed to dangerous levels of a known carcinogen by using the Recalled Sprays as intended and directed by Bayer. As noted above, many of the sprays directed users to apply the spray multiple times per day for prolonged periods of time, often weeks.

## IV. THE REFUND OFFERED BY BAYER IS INADEQUATE TO COMPENSATE CONSUMERS.

41. As part of the Recall Announcement, Bayer noted that "[c]onsumers may request a refund by visiting www.lotrimin.com … or www.tinactin.com" and that "[a] photo of the product will be required to receive a refund." Consumers that visit either website are asked to select which product they purchased, and provide their name, mailing address, email address, phone number, the lot number printed on the Recalled Spray cans, the number of Recalled Sprays purchased, and are required to upload a photo "[f]or each product that you are requesting a refund . . . [t]he photo(s) must show the Lot Number printed on the side or bottom of the can(s)."[33] Users cannot apply for, and therefore cannot receive, compensation for the benzene-tainted Recalled Sprays they purchased without providing a photos.

[32] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene
[33] https://www.livewell.bayer.com/en/spray-recall-refund

42. As described below, Bayer's refund offer is inadequate to compensate consumers for the harms caused by Bayer's conduct.

### A. BAYER REQUIES PHOTOGRAPHS OF PURCHASED RECALLED PRODUCTS TO ISSUE REFUNDS TO LIMIT THE EXPENSE OF THE RECALL.

43. Bayer is attempting to limit the expense of the recall by requiring that individuals (1) visit one of the two websites; (2) fill out the form; and (3) provide a photograph of each product for which consumers seek a refund for. This procedure improperly burdens consumers that have done nothing wrong and does not allow them to collect refunds for products purchased unless they are able to provide information regarding the purchase *and* provide a photograph of each product they purchased, even though some of the products are over three years old.

44. Consumers who cannot take photographs of the Recalled Sprays for any reason should not be excluded from receiving a refund. Consumers were harmed, and deprived of the benefit of the bargain, *at the point of purchase*. Requiring photos of used three-year old sprays is Bayer's attempt to limit the amounts it must pay to compensate individuals for their purchases of contaminated Recalled Sprays. It is noteworthy that other companies that have recalled aerosol spray products due to the presence of benzene have not required photographs of the products.[34]

45. Plaintiff thus seek relief beyond that offered by Bayer and seek refunds for every Recalled Spray sold during the Class Period.

[34] https://www.ccc-consumercarecenter.com/UCUConfiguration?id=a071i00000zs7tqAAA#etd=::00c?Z9W00Y00MVvu?,TV9Z00ww$; *see also* Coppertone Sunscreen Recall Claim Form: https://secure.sunscreenrecall2021.com/

## B. PLAINTIFF AND CLASS MEMBERS REQUIRE MEDICAL MONITORING

### i. PLAINTIFF AND CLASS MEMBERS HAVE A SIGNIFICANTLY INCREASED RISK OF CONTRACTING BENZENE-CAUSED CANCER BECAUSE THE RECALLED SPRAYS THEY REGULARLY USED EXPOSED THEM TO UNSAFE LEVEL OF BENZENE.

46. As alleged below, Plaintiff regularly used Recalled Sprays as directed on the Recalled Sprays' labels to treat medical conditions the Recalled Sprays are intended to treat such as athlete's foot, jock itch, and other conditions.

47. Plaintiff used Recalled Sprays manufactured and distributed by Bayer as directed by the Recalled Sprays' labels. As the labels included above show, this often meant that Plaintiff applied the Recalled Sprays multiple times a day for a period of time that could last as long as four weeks. These products, unbeknownst to Plaintiff, contained benzene, a known carcinogen.

48. Based on prevailing scientific evidence, and the classifications adopted by numerous agencies, regulatory bodies, and scientific organizations discussed *supra*, exposure to benzene via skin absorption can cause cancer, including leukemia and other blood-related cancers.

49. Thus, as a direct and proximate result of using Bayer's Recalled Sprays for years, Plaintiff is at a significantly increased risk of contracting Benzene-caused Cancers. Plaintiff's lengthy duration of exposure to benzene from Bayer's Recalled Sprays warrants additional medical testing not routinely provided to the public at large.

### ii. PLAINTIFF AND THE CLASS MEMBERS REQUIRE DIAGNOSTIC MEDICAL TESTING THAT DIFFERS FROM ROUTINE MEDICAL CARE

50. Physicians evaluate a person's exposure to toxic and carcinogenic substances, including benzene, when determining what diagnostic testing and treatment is necessary.

51. A reasonably prudent person would conclude that Plaintiff's repeated exposure to significant, unsafe levels of benzene over lengthy periods of time necessitates specialized testing (with resultant treatments) that is not generally given to the public at large as a part of routine medical care.

52. The available monitoring regime, discussed in greater detail below, is reasonably necessary and specific for individuals exposed to products known to significantly increase the risk of the Benzene-Caused Cancers because of exposure to benzene. It is different from that normally recommended in the absence of exposure to this risk of harm (whether in kind and/or frequency) and is not generally available in a general practitioner setting.

53. The available medical monitoring regime will mitigate the development of and health effects associated with the Benzene-Caused Cancers, improving prognosis, outcome, and quality of life, and reducing medical costs.

54. Consistent with best practices, Plaintiff seeks to implement a medical monitoring program which begins with screening to determine whether more invasive or costly tests are warranted. This screening may be conducted via questionnaire, in-person before a medical practitioner, or via a tele-health appointment.

55. Medical practitioners will review the questionnaire or the results of a screening appointment to determine whether additional testing, such as a blood test, for purposes of diagnosis

is required. Leukemia and other Benzene-Caused Cancers are typically found via blood tests and can be detected before symptoms begin.[35]

56. Additional testing may include blood tests and/or bone marrow tests.[36] Blood tests allow doctors to determine whether an individual has abnormal levels of red or white blood cells or platelets, which may suggest leukemia, or can show the presence of leukemia cells.[37] Bone marrow tests are used to determine whether leukemia cells which can avoid detection in blood tests are present.[38]

57. Screening and testing in the medical monitoring program will likely occur for an extended period of time. This permits the medical practitioners to monitor changes in symptoms or follow anomalies that may appear in tests over time, and accommodates latency periods associated with the Benzene-Caused Cancers.

## V. PLAINTIFF ALLEGATIONS

### A. PLAINTIFF VILLARREAL

58. Plaintiff Jose Villarreal is a citizen and resident of Boone County, Missouri.

59. Plaintiff Villarreal purchased and used Recalled Sprays during the Class Period, including Lotrimin Anti-Fungal (AF) Athlete's Foot Powder Spray.

60. Plaintiff Villarreal used each Recalled Spray he purchased as directed by the Recalled Spray product labels (as shown above).

61. Plaintiff Villarreal would not have purchased or used any Recalled Sprays had he known that the Recalled Sprays were at risk of, or did in fact, contain benzene.

[35] https://www.mayoclinic.org/diseases-conditions/leukemia/diagnosis-treatment/drc-20374378
[36] *Id.*
[37] *Id.*
[38] *Id.*

62. Plaintiff Villarreal was deprived of the benefit of the bargain when he purchased Recalled Sprays without knowing the Recalled Sprays were at risk of containing, or did in fact contain, benzene.

63. Plaintiff Villarreal requires medical monitoring to ensure that if he develops any Benzene-caused Cancers or other health conditions because of his use of Recalled Sprays the conditions are detected early to give him the best possible chance of having the condition resolve or be treated successfully.

## VI. CLASS ALLEGATIONS

64. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3).

### A. CLASSSES AND SUBCLASSES

65. Plaintiff seeks certification of the following Class and Subclass:

#### i. ECONOMIC LOSS CLASS AND SUBCLASSES

66. Plaintiff seeks class certification on behalf of a class defined as follows (the "Economic Loss Class"):

> **NATIONWIDE ECONOMIC LOSS CLASS:** All individuals who purchased a Recalled Spray in the United States during the Class Period.

67. Plaintiff seeks certification on behalf of a subclass defined as follows:

> **MISSOURI ECONOMIC LOSS SUBCLASS:** All individuals who were or are citizens of the State of Missouri who purchased Recalled Sprays during the Class Period (the "Missouri Economic Loss Subclass").

68. Plaintiff reserves the right to modify or refine the definitions of the Economic Loss Class or Missouri Economic Loss Subclass based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

### i. MEDICAL MONITORING CLASS AND SUBCLASS

69. Plaintiff seeks class certification on behalf of a class defined as follows (the "Nationwide Medical Monitoring Class"):

> **NATIONWIDE MEDICAL MONITORING CLASS**: All individuals who purchased and used Recalled Sprays in the United States and have not been diagnosed with a Benzene-caused Cancer or other health condition (the "Medical Monitoring Class").

70. Plaintiff seeks certification on behalf of a subclass defined as follows:

> **MISSOURI MEDICAL MONITORING SUBCLASS**: All individuals who were or are citizens of the State of Missouri who purchased and used a Recalled Spray and have not been diagnosed with a Benzene-caused Cancer or other health condition (the "Missouri Medical Monitoring Subclass").

71. Plaintiff reserves the right to modify or refine the definitions of the Nationwide Medical Monitoring Class or the State Missouri Medical Monitoring Subclass based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

## B. FED. R. CIV. P. 23 REQUIREMENTS

72. **Ascertainability**. The proposed Class and Subclass are readily ascertainable because they are defined using objective criteria so as to allow class members to determine if they are part of a Class or Subclass. Further, the Class and Subclass can be readily identified through records maintained by Bayer.

73. **Numerosity (Rule 23(a)(1))**. The Class and Subclass are so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class and Subclasses, as herein identified and described, is not known, upon information and belief there are millions of individuals who purchased the Recalled Sprays.

74. **Commonality (Rule 23(a)(2))**. Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class and Subclass members, including the following:

(a) whether the Recalled Sprays contain, or are likely to contain, or exposed the Class and Subclass to unacceptable levels of benzene;

(b) whether exposure to and consumption of Benzene increases the risk of developing any of the Benzene-caused Cancers;

(c) whether Bayer knew or should have known that the Recalled Sprays contained, or were likely to contain, unacceptable levels of benzene;

(d) whether Bayer knew or should have known that use of the Recalled Sprays increased the risk of developing any of the Benzene-caused Cancers;

(e) whether Bayer acted to conceal the fact that the Recalled Sprays expose users to unacceptable amounts of benzene;

(f) whether Bayer acted to conceal the fact that use of the Recalled Sprays increased the risk of developing cancer;

(g) whether Bayer was negligent in labeling, marketing, advertising, promoting and/or manufacturing and/or selling the Recalled Sprays;

(h) whether Bayer is liable for failing to warn of the risks associated with use of the Recalled Sprays;

(i) whether Plaintiff, members of the Nationwide Medical Monitoring Class, and members of the Missouri Medical Monitoring Subclass are entitled to medical monitoring relief as a result of their increased risk of developing the Benzene-Caused Cancers based on use of the Recalled Sprays; and

(j) the type and format of medical monitoring relief, declaratory relief and/or injunctive relief that is appropriate.

75. **Typicality (Rule 23(a)(3))**. Plaintiff's claims are typical of the claims of the proposed Class and Subclass. Plaintiff and the Class and Subclass (as applicable) suffered injuries as a result of Bayer's wrongful conduct that is uniform across the Class and Subclass.

76. **Adequacy (Rule 23(a)(4))**. Plaintiff has and will continue to fairly and adequately represent and protect the interests of the Class and Subclass. Plaintiff has retained counsel competent and experienced in complex litigation and class actions. Plaintiff has no interest that is antagonistic to those of the Class and Subclass, and Bayer have no defenses unique to Plaintiff. Plaintiff and their counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and Subclass, and they have the resources to do so. Neither Plaintiff nor Plaintiff's counsel have any interest adverse to those of the other members of the Class and Subclass.

77. **Substantial Benefits**. This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy and joinder of all members of the Class and Subclass is impracticable. The prosecution of separate actions by individual members of the Class and Subclass would impose heavy burdens upon the Courts and Bayer, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class and Subclass, and would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.

78. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual

members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

79. Class certification is also appropriate under Fed. R. Civ. P. 23(b)(2) because Bayer acted or refused to act on grounds generally applicable to the Class and Subclass, so that final injunctive relief or corresponding declaratory relief is appropriate as to the Class and Subclasses as a whole.

80. Plaintiff reserves the right to revise the foregoing class allegations and definitions based on facts learned and legal developments following additional investigation, discovery, or otherwise.

## CLAIMS FOR RELIEF

## FIRST CLAIM FOR RELIEF

### BREACH OF EXPRESS WARRANTY
### On Behalf of the Economic Loss Class or, alternatively, the Missouri Economic Loss Subclass

81. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

82. Bayer manufactured, distributed, and sold the Recalled Sprays into the stream of commerce with the intent that the Recalled Sprays would be purchased by Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass.

83. Bayer expressly warranted, advertised, and represented to Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass that the Recalled Sprays were safe and appropriate for human use.

84. Bayer made these express warranties regarding the Recalled Sprays quality and fitness for use in writing through its website, advertisements, and marketing materials and on the Recalled Sprays' packaging and labels. These express warranties became part of the basis of the

bargain that Plaintiff and the Class and Subclasses entered into upon purchasing the Recalled Sprays.

85. Bayer's advertisements, warranties, and representations were made in connection with the sale of the Recalled Sprays to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass relied on Bayer's advertisements, warranties, and representations regarding the Recalled Sprays in deciding whether to purchase Bayer's products.

86. Bayer's Recalled Sprays do not conform to Bayer's advertisements, warranties and representations in that they are not safe, healthy, and appropriate for human use.

87. Bayer therefore breached its express warranties by placing Recalled Sprays into the stream of commerce and selling them to consumers, when their use had dangerous effects and was unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Bayer. These associated health effects substantially impair the use, value, and safety of Recalled Sprays.

88. Bayer was aware, or should have been aware, of the presence of the human carcinogen benzene in the Recalled Sprays and therefore was aware or should have been aware of the toxic or dangerous health effects of the use of the Recalled Sprays, but nowhere on the package labeling or on Bayer's websites or other marketing materials did Bayer warn Plaintiff and members of the Economic Loss Class and Missouri Economic Loss Subclass and the presence of benzene in the Recalled Sprays or the dangers it posed.

89. Instead, Bayer concealed the presence of benzene in the Recalled Sprays and deceptively represented that the Recalled Sprays were safe, healthy, and appropriate for human

use. Bayer thus utterly failed to ensure that the material representations it was making to consumers were true.

90. Benzene was present in the Recalled Sprays when they left Bayer's possession or control and were sold to Plaintiff, members of the Economic Loss Class and Missouri Economic Loss Subclass. The dangers associated with use of the Recalled Sprays were undiscoverable by Plaintiff, members of the Economic Loss Class and Missouri Economic Loss Subclass at the time of purchase of the Recalled Sprays.

91. As manufacturers, marketers, advertisers, distributors, and sellers of Recalled Sprays, Bayer had exclusive knowledge and notice of the fact that the Recalled Sprays did not conform to the affirmations of fact and promises.

92. In addition, or in the alternative, to the formation of an express contract, Bayer made each of the above-described representations to induce Plaintiff and members of the Economic Loss Class and Missouri Economic Loss Subclass to rely on such representations.

93. Bayer's affirmations of fact and promises were material, and Plaintiff and members of the Economic Loss Class and Missouri Economic Loss Subclass reasonably relied upon such representations in purchasing the Recalled Sprays.

94. All conditions precedent to Bayer's liability for its breach of express warranty have been performed by Plaintiff or members of the Economic Loss Class or Missouri Economic Loss Subclass.

95. Affording Bayer an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Bayer had ample opportunity to test its products for benzene and to modify their manufacturing processes to ensure benzene was not present in the Recalled Sprays to

make them safe and healthy for use by Plaintiff and members of the Economic Loss Class and Subclasses, or recall them, but failed to do so until now.

96. As a direct and proximate result of Bayer's breaches of express warranty, Plaintiff and members of the Class and Subclass have been damaged because they did not receive the products as specifically warranted by Bayer. Plaintiff and members of the Economic Loss Class and Missouri Economic Loss Subclass did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for the Recalled Sprays.

97. Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Bayer's failure to deliver goods conforming to their express warranties and resulting breach.

## SECOND CLAIM FOR RELIEF

### BREACH OF IMPLIED WARRANTY
### On Behalf of the Economic Loss Class or, alternatively, the Missouri Economic Loss Subclass

98. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

99. Bayer is a merchant engaged in the sale of goods to Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass.

100. There was a sale of goods from Bayer to Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass.

101. At all times mentioned herein, Bayer manufactured, distributed, or supplied Recalled Sprays, and prior to the time the Recalled Sprays were purchased by Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass, Bayer impliedly warranted to them that the Recalled Sprays were of merchantable quality, fit for their ordinary use, and conformed to

the promises and affirmations of fact made on the Recalled Sprays' labels and packaging, including that the Recalled Sprays were safe and appropriate for human use. Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass relied on Bayer's promises and affirmations of fact when they purchased the Recalled Sprays.

102. Contrary to these representations and warranties, the Recalled Sprays were not fit for their ordinary use, and did not conform to Bayer's affirmations of fact and promises as use of the Recalled Sprays was accompanied by the risk of exposure to benzene and to developing Benzene-caused Cancers which does not conform to the packaging.

103. Bayer breached its implied warranties by selling Recalled Sprays that failed to conform to the promises or affirmations of fact made on the packaging or label as use of each Recalled Sprays was accompanied by the risk of exposure to benzene and to developing Benzene-caused Cancers which does not conform to the packaging.

104. Bayer was, or should have been on notice of this breach, as it was on notice that the process used to manufacture the Recalled Sprays was likely to result in the presence of benzene in the Recalled Sprays.

105. Privity exists because Bayer impliedly warranted to Plaintiff and the Economic Loss Class and Missouri Economic Loss Subclass through the warranting, packaging, advertising, marketing, and labeling that Recalled Sprays were natural, and suitable for use to treat health conditions by individuals, and made no mention of the attendant health risks associated with use of the Recalled Sprays.

106. As a direct and proximate result of Bayer's conduct, Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass have suffered actual damages in that each Recalled Spray they purchased is worth less than the price they paid and that they would not have

purchased at all had they known of the attendant health risks associated with the use of each Recalled Spray.

107. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Bayer's failure to deliver goods conforming to their implied warranties and resulting breach.

## THIRD CLAIM FOR RELIEF

### FRAUDULENT MISREPRESENTATION
### On Behalf of the Economic Loss Class or, alternatively, the Missouri Economic Loss Subclass

108. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

109. Bayer falsely represented to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass that the Recalled Sprays did not contain unsafe levels of carcinogens and were safe for human use.

110. Bayer intentionally, knowingly, and recklessly made these misrepresentations to induce Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass to purchase Recalled Sprays.

111. For at least part of the Class Period, Bayer knew that its representations about the Recalled Sprays were false, or that there was a significantly likelihood that they were false, in that the Recalled Sprays either did contain, or had a significant risk of containing unsafe amounts of the carcinogen benzene which does not conform to the products' labels, packaging, advertising, and statements. Bayer knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass.

112. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass did in fact rely on these misrepresentations and purchased Recalled Sprays to their detriment. Given the deceptive manner in which Bayer advertised, represented, and otherwise promoted the Recalled Sprays, the reliance Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass placed on Bayer's misrepresentations was justifiable.

113. As a direct and proximate result of Bayer's conduct, Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass have suffered actual damages in that they purchased Recalled Sprays that were worth less than the price they paid and that they would not have purchased at all had they known of the risk of the presence of unsafe levels of benzene in the Recalled Sprays and the health risks, including cancer, associated with the use of the Recalled Sprays that does not conform with the Recalled Sprays' labels, packaging, advertising, and statements.

114. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

## FOURTH CLAIM FOR RELIEF

### FRAUD BY OMISSION
### On Behalf of the Economic Loss Class or, alternatively, the Missouri Economic Loss Subclass

115. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

116. Bayer concealed from and failed to disclose to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass that use of Recalled Sprays is accompanied by a risk of exposure to the carcinogen benzene which carries with it the risk of developing Benzene-caused Cancers which does not conform to the products' labels, packaging, advertising, and statements.

117. Bayer was under a duty to disclose to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass the true safety, quality, characteristics, fitness for use, and suitability of the Recalled Sprays because: (1) Bayer was in a superior position to know the true state of facts about its products; (2) Bayer was in a superior position to know the risks associated with the use of, characteristics of, and suitability of Recalled Sprays for use by individuals; and (3) Bayer knew that Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass could not reasonably have been expected to learn or discover that Recalled Sprays were misrepresented in the packaging, labels, advertising, and websites prior to purchasing Recalled Sprays.

118. The facts concealed or not disclosed by Bayer to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass were material in that a rea sonable consumer would have considered them important when deciding whether to purchase Recalled Sprays.

119. Plaintiff and the Class and Subclasses justifiably relied on the Bayer's omissions to their detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of Recalled Sprays, which is inferior when compared to how Recalled Sprays are advertised and represented by Bayer.

120. As a direct and proximate result of Bayer's conduct, Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass have suffered actual damages in that they purchased Recalled Sprays that were worth less than the price they paid and that they would not have purchased at all had they known of the health risks associated with the use of the Recalled Sprays which do not conform to the Recalled Sprays' labels, packaging, advertising, and statements.

121. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

## FIFTH CLAIM FOR RELIEF

### NEGLIGENT MISREPRESENTATION
### On Behalf of the Economic Loss Class or, alternatively, the Missouri Economic Loss Subclass

122. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

123. Bayer had a duty to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of Recalled Sprays.

124. Bayer breached its duty to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass that did not have the qualities, characteristics, and suitability for use as advertised by Bayer and by failing to promptly remove Recalled Sprays from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Sprays.

125. Bayer knew or should have known that the qualities and characteristics of the Recalled Sprays were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Bayer, yet continued selling the Recalled Sprays. Specifically, Bayer knew or should have known that: (1) the manufacturing process used to produce the Recalled Sprays resulted in the presence of benzene in the Recalled Sprays or a substantial risk

that benzene would be found in the Recalled Sprays and (2) the Recalled Sprays were otherwise not as warranted and represented by Bayer.

126. As a direct and proximate result of Bayer's conduct, Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass have suffered actual damages in that they purchased Recalled Sprays that were worth less than the price they paid and that they would not have purchased at all had they known they contained the carcinogen benzene that is known to cause the Benzene-caused cancers which does not conform to the products' labels, packaging, advertising, and statements.

127. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available.

## SIXTH CLAIM FOR RELIEF

### UNJUST ENRICHMENT
### On Behalf of the Economic Loss Class or, alternatively, the Missouri Economic Loss Subclass

128. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

129. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass conferred substantial benefits on Bayer through their purchase and use of Recalled Sprays. Bayer knowingly and willingly accepted and enjoyed these benefits.

130. Bayer either knew or should have known that the payments rendered by Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass were given with the expectation that the Recalled Sprays would have the qualities, characteristics, and suitability for use represented and warranted by Bayer. As such, it would be inequitable for Bayer to retain the benefit of the payments under these circumstances.

131. Bayer's acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Bayer to retain the benefits without payment of the value to Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass.

132. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass are entitled to recover from Bayer all amounts wrongfully collected and improperly retained by Bayer, plus interest thereon.

133. Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

## SEVENTH CLAIM FOR RELIEF

### NEGLIGENT FAILURE TO WARN
### On Behalf of the Medical Monitoring Class or, alternatively, the Missouri Medical Monitoring Subclass

134. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

135. Under the laws of Missouri, manufacturers, including Bayer, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution. Bayer breached this duty for its Recalled Sprays. The warnings included on were inadequate because they did not warn of the presence of benzene in the Recalled Sprays, of the substantial risk that benzene was in the Recalled Sprays, or of the fact that exposure to benzene can result in the development of the Benzene-caused Cancers.

136. Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass or their doctors would have read and heeded these warnings had they been included on the labels and packaging of the Recalled Sprays. Had such warnings been provided, Plaintiff, the

Medical Monitoring Class, and the Missouri Medical Monitoring Subclass would have been made aware of the risks of developing the Beneze-caused Cancers associated with exposure to the carcinogen benzene found in the Recalled Sprays.

137. As a direct and proximate result of Bayer's failure to provide adequate warnings of the risk of exposure to benzene and the risk of development of Benzene-caused Cancers through exposure to benzene, Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass have sustained a significantly increased risk of developing serious and potentially fatal Benzene-caused Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

138. The latent injuries from which Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Benzene-caused Cancers of using Recalled Sprays and is different from that normally recommended in the absence of exposure to this risk of harm.

139. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Benzene-caused Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Benzene-caused Cancers.

140. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Benzene-caused Cancers.

141. By monitoring and testing Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass, the risk of developing and losses arising from suffering from long-term injuries, disease will be significantly reduced.

142. Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass seek creation of a Court-supervised, Bayer-funded medical monitoring program which will facilitate the diagnoses of Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass for the Benzene-caused Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass as frequently and appropriately as necessary.

143. Accordingly, Bayer should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has used the Recalled Sprays for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all members of the Medical Monitoring Class and the Missouri Medical Monitoring Subclass in writing that they may require frequent medical monitoring for the purpose of diagnosis.

144. Plaintiff, the Medical Monitoring Class, and the Missouri Medical Monitoring Subclass have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to using the Recalled Sprays tainted with the carcinogen benzene. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff, the Medical Monitoring Class, the State Missouri Medical Monitoring Subclass will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

## EIGHTH CLAIM FOR RELIEF

**NEW JERSEY CONSUMER FRAUD ACT**
**N.J. Stat. Ann. §§ 56:8-1, *et seq.***
**On behalf of Plaintiff, the Economic Loss Class, and the Missouri Economic Loss Subclass**

145. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

146. New Jersey's Consumer Fraud Act ("New Jersey CFA") prohibits any "act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise." *See* N.J. Stat. Ann. §56:8-2.

147. At all relevant times, Plaintiff, Economic Loss Subclass, Economic Loss Subclass members, and Bayer were "persons" within the meaning of the New Jersey CFA. *See* N.J. Stat. Ann. § 56:8-1(d).

148. Bayer willfully and purposefully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts they intended others to rely upon in connection with the sale of the merchandise as defined by N.J. Stat. Ann. § 56:8-1(c) in violation of N.J. Stat. Ann. § 56:8-2 as described in the allegations above.

149. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above were acts or practices in the conduct of trade or commerce.

150. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above impact the public interest.

151. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above were unfair because they inequitably enriched Bayer at the expense of Plaintiff and the Economic Loss Class.

152. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above were unfair because they offended public policy, and were so oppressive that Plaintiff and the Economic Loss Class had little alternative but to submit, which caused consumers substantial injury.

153. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays were unfair in that they violated the well-established public policies of protecting consumers from avoidable dangers and that the manufacturer of products is responsible for ensuring that they are fit for human use.

154. Plaintiff and the Economic Loss Class have suffered economic injury as a direct and proximate result of Bayer's conduct.

155. As a direct and proximate result of the foregoing acts and practices, Bayer has received, or will receive, income, profits, and other benefits which it would not have received if it had not engaged in the violations described in this Complaint.

156. As a result, Plaintiff and the Economic Loss Class seek relief including, *inter alia*, refund of amounts recovered by Bayer for the Recalled Sprays, injunctive relief, damages, treble damages, attorney's fees, and costs pursuant to N.J. Stat. Ann. §§ 56:8-2.11 and 56:8-19.

## THIRTEENTH CLAIM FOR RELIEF

### MISSOURI MERCHANDISING PRACTICES ACT
### Mo. Rev. Stat. Ann. §§ 407.010, *et seq.*
### On Behalf of Plaintiff Jose Villarreal and the Missouri Economic Loss Subclass

157. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

158. Missouri's Merchandising Practices Act ("Missouri MPA") prohibits any "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material

fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose."

159. At all relevant times, Bayer and members of the Missouri Economic Loss Subclass were "persons" within the meaning of the Missouri MPA. *See* Mo. Rev. Stat. Ann. § 407.010(5).

160. Bayer willfully and purposefully engaged in deceptive and unfair acts and practices, misrepresentation, and the concealment, suppression, and omission of material facts in connection with trade or commerce in violation of Mo. Rev. Stat. Ann. § 407.020 as described in the allegations above.

161. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above are acts or practices in the conduct of trade or commerce.

162. At all relevant times, Plaintiff Jose Villarreal and the Missouri Economic Loss Subclass acted as reasonable consumers would in light of all circumstances.

163. Bayer's unlawful method, acts, and practices as alleged would cause a reasonable person to enter into the transactions that resulted in damages.

164. At trial, Plaintiff Jose Villarreal will present, both individually and on behalf of the Plaintiff Jose Villarreal and the Missouri Economic Loss Subclass, evidence that is sufficiently definitive and objective to allow the loss of individual damages to be calculated with a reasonable degree of certainty.

165. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above impacts the public interest.

166. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above were unfair because they inequitably enriched Bayer at the expense of Plaintiff Jose Villarreal and the Missouri Economic Loss Subclass.

167. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above were unfair because they offend public policy, and were so oppressive that the Plaintiff Jose Villarreal and the Missouri Economic Loss Subclass had little alternative but to submit, which caused consumers substantial injury.

168. Bayer's misrepresentations and omissions in the sale of the Recalled Sprays detailed above were unfair in that they violated the well-established public policies of protecting consumers from avoidable dangers and that the manufacturer of medical devices is responsible for ensuring that they are safe for human use.

169. Plaintiff Jose Villarreal and the Missouri Economic Loss Subclass suffered economic injury as a direct and proximate result of Bayer's conduct.

170. As a direct and proximate result of the foregoing acts and practices, Bayer received, or will receive, income, profits, and other benefits which they would not have received if they had not engaged in the violations described in this Complaint.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, pray for judgment against Bayer as to each and every count, including:

A. An order certifying this action as a class action, certifying the Classes and Subclasses requested herein, designating Plaintiff as the representatives of the Classes and Subclass, and appointing Plaintiff's counsel as counsel to the Classes and Subclasses;

B. An order declaring that Bayer's actions constitute: (i) breach of express warranty; (ii) breach of the implied warranty of merchantability; (iii) fraudulent misrepresentation; (iv) fraud by omission; and (v) negligence; (vi) unjust enrichment; and (vii) unfair and

deceptive business practices in violation of Missouri and New Jersey consumer protection statutes, and that Bayer is liable to Plaintiff, members of the Classes, and members of the Subclasses, as described herein, for damages arising therefrom;

C. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Bayer from continuing the unlawful practices alleged herein, and injunctive relief to remedy Bayer's past conduct;

D. A judgment awarding Plaintiff and members of the Classes and Subclass all appropriate damages, in an amount to be determined at trial;

E. A judgment awarding equitable, injunctive, and/or declaratory relief as may be appropriate including, but not limited to, restitution, disgorgement, and requiring Bayer to develop, implement, and maintain a medical monitoring program as detailed above for members of the Class and Subclass.

F. A judgment awarding Plaintiff and members of the Classes and Subclass prejudgment and post-judgment interest, as permitted by law;

G. A judgment awarding Plaintiff and members of the Classes and Subclass costs and fees, including attorneys' fees, as permitted by law; and

H. Grant such other legal, equitable or further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury for all issues so triable.

DATED: November 17, 2021

Respectfully submitted,

By: */s/ Tim E. Dollar*
Tim E. Dollar, MO Bar #: 33123

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